REMARKS

I. Status of the Claims

Claims 37-44, 53-60, 65-66 and 71-73 have been cancelled without waiver, prejudice or disclaimer. Claims 36, 45-48, 50-52 and 70 have been amended to recite the lentivirus as the FIV-141 virus, the mutated gene as ENV, and/or the mammal as a cat. Support for the amendment to the claims can be found in the claims as originally filed and on, for example, page 5, lines 1-2; page 5, lines 31-36; page 6, lines 32-33; page 12, Table 1; page 27, line 27 through page 28, line 2; and page 35, lines 5-10 of the specification. No new matter has been added by the present amendment. Upon entry of this amendment, claims 36, 45-48, 50-52, 61 and 70 will be pending.

II. First Rejection Under 35 U.S.C. § 112, second paragraph

Claims 36-44 and 52 and 53 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the term "significantly reduced infectivity" of claims 36 and 52 is a relative term which renders the claim indefinite.

This rejection has been rendered moot in part by the cancellation of claims 37-44 and 53. With respect to remaining claims 36 and 52, this rejection has been rendered moot by the present amendment. Claims 36 and 52 have been amended to recite "...significantly reduced infectivity to feline T lymphocytes relative to the wild type FIV-141 virus..." (claim 36) and "...significantly reduced infectivity to feline T lymphocytes relative to FIV-141 virus made from the unmutated, wild type nucleic acid." (claim 52). Applicants respectfully request this rejection be withdrawn.

III. Second Rejection Under 35 U.S.C. § 112, second paragraph

Claims 56-60 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been rendered moot by the cancellation of claims 56-60. Applicants respectfully request this rejection be withdrawn.

IV. First Rejection Under 35 U.S.C. § 112, first paragraph

Claims 36-44 and 51-61 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention. This rejection has been rendered moot, in part, by the cancellation of claims 37-44 and 53-60 and, in part, by the amendment of claims 36 and 51 to recite the gene to be mutated as the ENV gene with respect to an FIV-141 virus. Applicants respectfully request this rejection be withdrawn.

V. Second Rejection Under 35 U.S.C. § 112, first paragraph

Claims 56-60 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection has been rendered moot by the cancellation of claims 56-60. Applicants respectfully request this rejection be withdrawn.

VI. Rejection Under 35 U.S.C. § 102(b)

Claims 36-44, 51, 52, 54, 55 and 61 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Looney et al. (WO 94/174825).

This rejection has been rendered moot, in part, by the cancellation of claims 37-44 and 54-55. With respect to remaining claims 36, 51 and 61, Applicants respectfully traverse this rejection.

As amended, Applicants' claimed invention relates to a method of making an attenuated FIV-141 virus or a nucleic acid molecule encoding an attenuated FIV-141 virus; an attenuated FIV-141 virus or a nucleic acid molecule encoding an attenuated FIV-141 virus produced by the claimed method; a host cell and vaccine based on an attenuated FIV-141 virus or a nucleic acid molecule encoding an attenuated FIV-141 virus produced by the claimed method; a method of producing a nucleic acid molecule suitable for use in a vaccine for FIV-141 virus; a host cell infected with a nucleic acid molecule prepared by the claimed method; and a method of inducing an immune response based on the claimed vaccine.

The claims as amended recite mutation of solely the ENV gene. As set forth on page 40, line 20 through page 41, line 3 and in Figure 11, mutation of the ENV gene produces unexpected and superior results relative to mutation of other genes. As such, Applicants contend that the claimed invention is novel and unobvious in view of WO 97/32983.

WO 97/32983 describes a live-attenuated feline immunodeficiency virus (FIV), and recombinant vectors for producing them, useful as vaccines and therapeutic agents against FIV and diseases associated with virulent FIV infection. Abstract. According to WO 97/32983, in the recombinant vectors and FIVs, one or more genes, or part of the gene(s), responsible for FIV pathogenesis has been completely or partially rendered nonfunctional, *e.g.*, by full or partial deletion or mutagenesis. Abstract. WO 97/32983 exemplifies a multitude of genes for such full or partial deletion or mutagenesis. WO 97/32983, page 10, lines 7-22. However, Applicants' claimed invention can be distinguished since WO 97/32983 provides only a general teaching of possible gene mutations and fails to provide one of skill in the art with any guidance as to how to pick and choose among the list of possible gene mutations. A reading of WO 97/32983 as a whole would lead one of skill in the art to believe that mutation of the ENV gene would render the same results as mutation of any of the other listed genes. However, by the data illustrated in Figure 11, Applicants show that mutation of the ENV gene produces an attenuated virus that exhibits greater efficacy against wild-type FIV-141 virus infection. WO 97/32983 does not teach or suggest such unexpected results. Thus Applicants' claimed invention is neither anticipated nor rendered obvious by WO 97/32983. Applicants respectfully request this rejection be withdrawn.

VII. Conclusion

Applicants respectfully request reconsideration of the subject application in view of the above remarks. The subject application is now in condition for allowance and early notice to that effect is respectfully solicited.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of

this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 16-1445. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

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MARKED-UP VERSION OF THE CLAIMS

--36. (Amended) A method of making an attenuated FIV-141 virus ~~lentivirus~~ that replicates upon entry into a host cell but which exhibits ~~in host cells but that has~~ significantly reduced infectivity to feline T lymphocytes relative to the ~~its~~ wild type FIV-141 virus ~~counterpart~~, or a nucleic acid molecules encoding said attenuated FIV-141 virus ~~lentivirus~~, comprising mutating an ENV gene ~~one gene selected from the group consisting of: Vif, MA, ORF(2), ENV, CA, NC, SU, TMf, CT, IN, DU, V3/4, V7/8, and RRE, or by mutating each of the gene pairs selected from the group consisting of: MA/TMf, MA/V3/4, MA/Vif and ENV/IN~~.

45. (Amended) An attenuated FIV-141 virus ~~lentivirus~~ produced by the method of claim 36.

46. (Amended) A nucleic acid molecule encoding the attenuated FIV-141 virus ~~lentivirus~~ of claim 45.

47. (Amended) A host cell infected with the attenuated FIV-141 virus ~~lentivirus~~ of claim 45.

48. (Amended) An attenuated whole virus vaccine, comprising the attenuated FIV-141 virus of claim 45, and a pharmaceutically acceptable carrier.

50. (Amended) A vaccine comprising the nucleic acid molecule of claim 46 at a concentration sufficient to induce immunity when administered to a cat ~~mammal~~, and a pharmaceutically acceptable carrier.

51. (Amended) A method of producing a nucleic acid molecule suitable for use in a vaccine for FIV-141 virus ~~lentivirus~~ infection, comprising:

a) reverse transcribing said FIV-141 virus's ~~lentivirus's~~ genomic RNA;

b) cloning the reverse transcript of step (a);

c) mutating the ENV gene ~~one or more genes~~ in the cloned nucleic acid of step (b)~~, wherein said genes are selected from the group consisting of MA, CA, NC, SU, TMf, ORF(2), CT, ENV, V3/4, V/78, Vif, Vifn, Vifc, IN, DU, and RRE~~; and

d) cloning the mutated nucleic acid of step (c).

52. (Amended) The method of claim 51, wherein the mutated nucleic acid molecule, upon introduction into a host cell, produces an attenuated FIV-141 virus that replicates but which exhibits ~~that has~~ significantly reduced infectivity to feline T-lymphocytes relative to FIV-141 virus ~~lentivirus~~ made from the unmutated, wild type nucleic acid.

61. A host cell infected with a nucleic acid molecule prepared by the method of claim 51.

70. (Amended) A method of inducing an immune response in a cat ~~mammal~~, comprising administering the vaccine of claim 48 to said cat ~~mammal~~ at a dosage sufficient to induce protective immunity against subsequent infection with at least one strain of said FIV-141 ~~lentivirus~~.